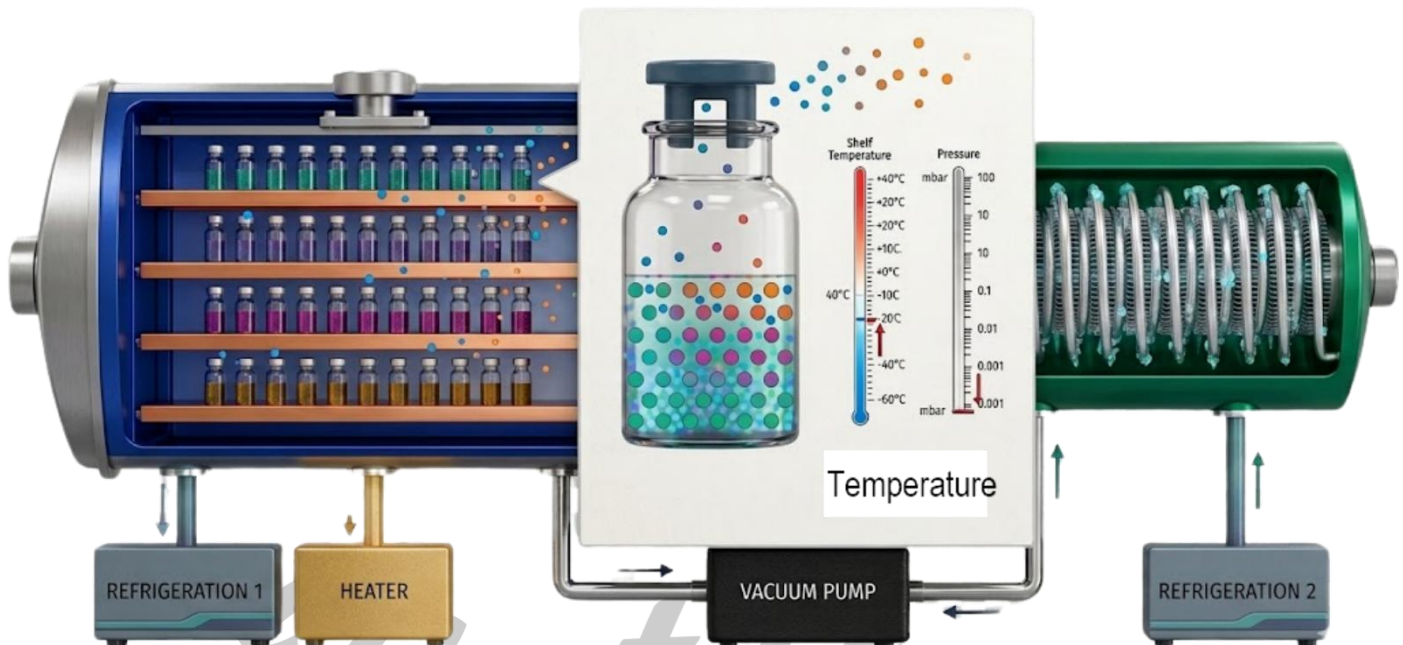


Lyophilization

Principles of Lyophilization (Freeze Drying)

- Lyophilization, also called freeze drying, is a process used to remove water from a product after it is frozen, under low pressure (vacuum), so that the ice converts directly into vapor without passing through the liquid state.



- This process is widely used for heat-sensitive drugs such as proteins, vaccines, and injectables.

Basic Principle: Sublimation

- Sublimation is the direct conversion of solid (ice) into vapor without becoming liquid.
- This happens under:**
 - Low temperature
 - Low pressure (vacuum)

Why Lyophilization is Used:

- Prevents degradation of heat-sensitive drugs
- Improves stability and shelf-life
- Allows easy reconstitution (adding water before use)

Key Scientific Concepts

1. Sublimation

- Ice → vapor directly
- Requires low pressure and controlled heat

2. Vapor Pressure Difference

- Water moves from product (higher vapor pressure) to condenser (lower vapor pressure)

3. Heat and Mass Transfer

- Heat is supplied to provide energy for sublimation
- Vapor is removed from product surface

4. Phase Diagram of Water

- Important to understand freezing and sublimation conditions
- Triple point: where solid, liquid, and vapor coexist

Critical Factors in Lyophilization

- Temperature (must be low to avoid melting)
- Pressure (vacuum required)
- Product composition
- Ice crystal size (affects drying rate)

Advantages:

- Preserves drug activity
- Produces porous structure for quick reconstitution
- Long shelf life

Disadvantages:

- Expensive process
- Time-consuming
- Requires specialized equipment

Process of Lyophilization (Freeze Drying Process)

The lyophilization process consists of three major stages.

1. Freezing Stage

- Product solution is filled into vials
- Cooled to very low temperature (e.g., -40°C or lower)
- Water forms ice crystals
- **Important Points:**
 - Slow freezing → large ice crystals → better drying

- Fast freezing → small crystals → slower drying

2. Primary Drying (Sublimation Stage)

- Pressure is reduced using vacuum
- Heat is applied slowly
- Ice converts directly into vapor
- **Key Points:**
 - About 90% of water is removed
 - Product remains in solid state
 - Temperature must not exceed collapse temperature

3. Secondary Drying (Desorption Stage)

- Removes remaining bound moisture
- Temperature is slightly increased
- Moisture content reduced to very low level (1–2%)

Final Step: Sealing

- Vials are sealed under vacuum or inert gas
- Prevents moisture entry

Important Process Parameters:

- Shelf temperature
- Chamber pressure
- Drying time
- Product thickness

Freeze Drying Equipment

- Freeze drying requires specialized equipment designed to maintain low temperature and vacuum conditions.

Main Components:

1. Drying Chamber

- Contains shelves where product is placed
- Shelves can be heated or cooled

2. Condenser

- Collects water vapor

- Maintained at very low temperature
- Prevents vapor from reaching vacuum pump

3. Vacuum System

- Creates low pressure inside chamber
- Essential for sublimation

4. Refrigeration System

- Provides cooling for freezing and condenser

5. Control System

- Monitors temperature, pressure, and time

Types of Freeze Dryers:

1. Tray Freeze Dryer

- Product placed in trays
- Used for bulk materials

2. Vial Freeze Dryer

- Used for injectable products
- Vials are directly dried and sealed

3. Continuous Freeze Dryer

- Used for large-scale production
- Continuous operation

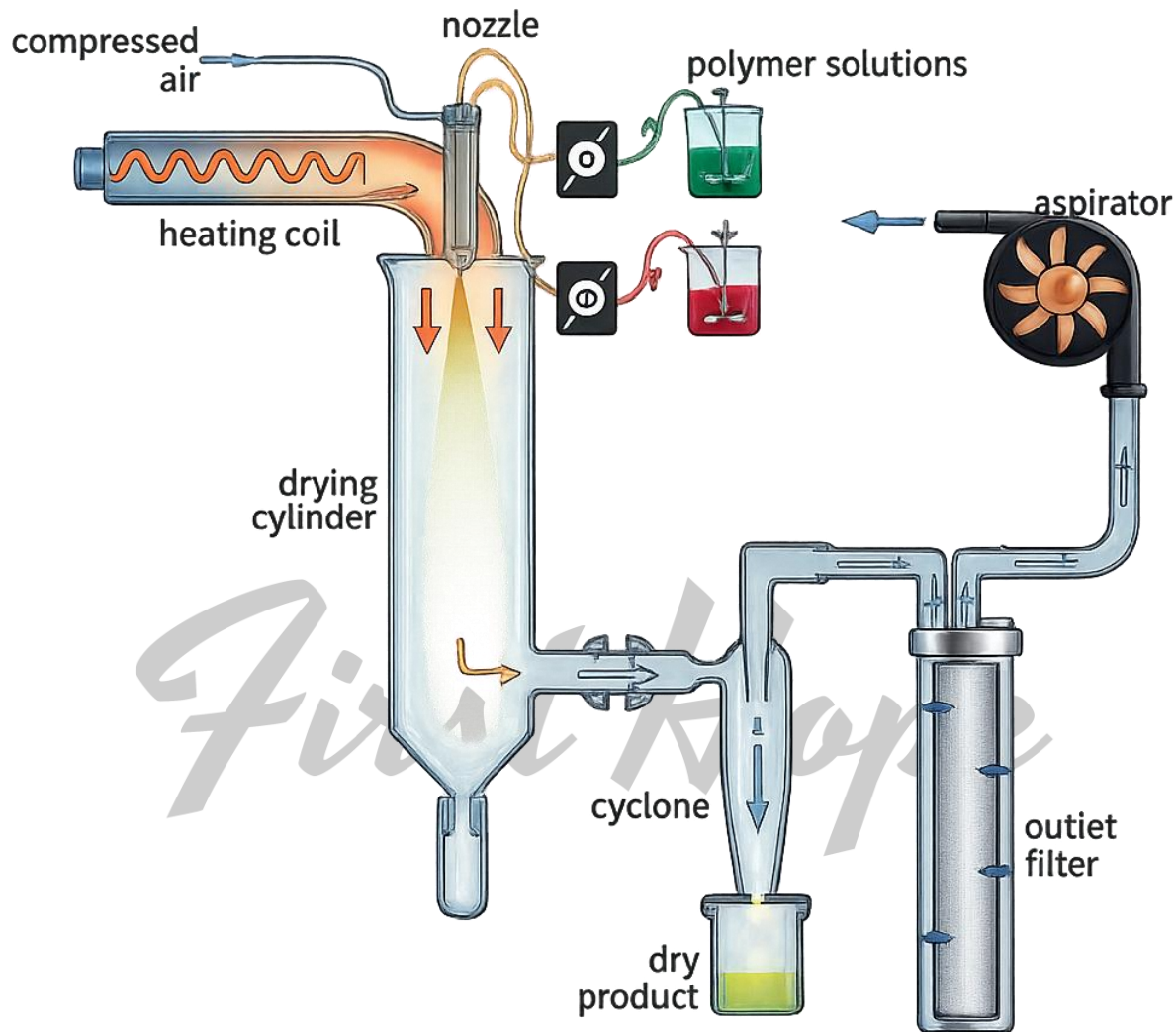
Features:

- Stainless steel construction
- Sterile design for pharmaceutical use
- Automated control systems

Spray drying Technology

Principles of Spray Drying

- Spray drying is a process in which a liquid solution or suspension is converted into dry powder by rapidly drying it with hot air.



Basic Principle:

- Liquid is atomized into fine droplets
- Droplets come in contact with hot air
- Water evaporates quickly
- Dry particles are formed

Key Steps:

1. Atomization
2. Drying
3. Particle collection

Why Spray Drying is Used:



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